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**BY ELECTRONIC FILING
ON THE PUBLIC DOCKET**

The Honorable P. Kevin Castel
United States District Court for the
Southern District of New York
Daniel Patrick Moynihan Courthouse
500 Pearl Street
New York, New York 10007

Re: ***Novartis Pharma AG v. Amgen, Inc., 19 CV 2993 – Novartis Pharma AG’s Response to Amgen Inc.’s May 14, 2019 Pre-Motion Letter***

Dear Judge Castel:

We, along with White & Case LLP, are counsel for Plaintiff and Counterclaim Defendant Novartis Pharma AG (“Novartis Pharma”) in the above-referenced litigation. We respectfully submit this response to Amgen Inc.’s (“Amgen”) May 14, 2019 letter seeking leave to file a motion to strike, or in the alternative treat as denials, the Affirmative Defenses Novartis Pharma asserted to Amgen’s Counterclaims. [See Dkt. No. 23]. The parties’ initial case management conference is scheduled for June 12, 2019 at 12:00 p.m.

Initially, Amgen’s application to file a motion at this early stage of the litigation to eliminate seven affirmative defenses contravenes Rule 1 of the Federal Rules of Civil Procedure because it calls for unnecessary motion practice that would not dispose of any of the central issues in the case.¹

In any event, the legal grounds for Amgen’s proposed motion are weak and Novartis Pharma’s Affirmative Defenses are amply supported by the facts set forth in the pleadings.

¹ The Federal Rules of Civil Procedure should be “construed, administered, and employed by the court and the parties to secure the just, speedy, and inexpensive determination of every action and proceeding.” Fed. R. Civ. P. 1.

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First, “[m]otions to strike an affirmative defense are generally disfavored.” *City of New York v. FedEx Ground Package Sys., Inc.*, No. 13 CIV. 9173 (ER), 2017 WL 633445, at *2 (S.D.N.Y. Feb. 14, 2017) (internal quotation marks and citations omitted). See also *Estee Lauder, Inc. v. Fragrance Counter, Inc.*, 189 F.R.D. 269, 271 (S.D.N.Y. 1999) (“It is well-established in this Circuit that a motion to strike an affirmative defense under Rule 12(f), Fed.R.Civ.P. for legal insufficiency is not favored.”) (internal quotation marks and citations omitted). As a result, courts in this Circuit have noted that they are reluctant to “tamper with the pleadings unless there is a strong reason for so doing,” *FedEx*, 2017 WL 633445, at *2 (quoting *Lipsky v. Commonwealth United Corp.*, 551 F.2d 887, 893 (2d Cir. 1976)).

Second, Amgen’s reliance on *GEOMC Co. v. Calmare Therapeutics Inc.*, 918 F.3d 92, 98 (2d Cir. 2019) is misplaced. Amgen cites *GEOMC* for the proposition that Novartis Pharma’s Affirmative Defenses are deficient because they allegedly contain insufficient factual bases.² But Novartis Pharma’s Complaint [Dkt. No. 1] and Answer to Amgen’s Counterclaims [Dkt. No. 19] contain ample factual support,³ including particularized allegations showing that:

1. Amgen has taken steps to unjustifiably terminate the 2015 Agreement⁴ even though Sandoz’ contract manufacturing agreement with Alder does not constitute a “material breach” of that Agreement, and Amgen has sought to terminate the 2017 Agreement on the same deficient grounds, notwithstanding that the 2017 Agreement *does not contain* a “Distracting Program” provision. Amgen has also

² Amgen makes this argument despite the fact that its own affirmative defenses in its Answer and Counterclaims to Novartis Pharma’s Complaint are, like Novartis Pharma’s, single-sentence statements of the affirmative defense, without any additional factual allegations contained in that section of the pleading. [Dkt. No. 13 at p. 57]. In addition, their affirmative defenses—material breach and unclean hands—are the same as two of Novartis Pharma’s affirmative defenses that Amgen attacks in its letter-motion.

³ Moreover, there has been no prejudice to Amgen as a result of Novartis Pharma’s timely filed Affirmative Defenses. See *GEOMC*, 918 F.3d at 98–99 (“Whether the third of the *McCaskey* factors, prejudice, should be a basis for dismissing or opposing the addition of an otherwise valid affirmative defense will normally depend on when the defense is presented.”) (referring to *S.E.C. v. McCaskey*, 56 F.Supp.2d 323 (S.D.N.Y. 1999)).

⁴ This letter uses the same defined terms as Novartis Pharma’s Complaint. [Dkt. No. 1].

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suffered no damages, a necessary element of its breach of contract claim. (Affirmative Defense 1: Amgen's Counterclaims fail to state a claim upon which relief can be granted);

2. Amgen's attempt to terminate the Agreements without justification constitutes a material breach. (Affirmative Defense 2: Amgen's Counterclaims are barred by Amgen's breaches of the Collaboration Agreements);

3. Amgen has materially benefited from Novartis Pharma's investments into the development and commercialization of Aimovig, while Novartis Pharma has not been adequately compensated. Thus, any award Amgen receives would unjustly enrich it. (Affirmative Defense 3: Any award to Amgen would constitute unjust enrichment);

4. Amgen seeks to terminate the Agreements without making any reasonable effort to quantify its damages, much less to mitigate them. (Affirmative Defense 4: Amgen failed, refused, or neglected to mitigate the damages of which it complains, if any);

5. Amgen's allegations regarding Novartis Pharma's alleged breach of the Agreements represent nothing more than a thinly veiled pretext for its desire to reap all of the benefits of Novartis Pharma's substantial investment in the success of Aimovig without sharing any of the profits as contemplated under the Agreements. (Affirmative Defense 5: Amgen's Counterclaims are barred by the doctrine of unclean hands);

6. Amgen has sought to terminate the Agreements and seeks damages without specifying how it has been "damaged" by Sandoz' provision of contract manufacturing to Alder, whose product has not yet entered the market. (Affirmative Defense 6: Amgen's Counterclaims are barred because Amgen's alleged damages, if any, are speculative and uncertain); and

7. Amgen's attempt to terminate the Agreements is improper because the Agreements are far more valuable than any supposed damages Amgen may eventually incur by virtue of Alder's product entering the market in the future. (Counterclaim 7: Amgen's Counterclaims are barred because the relief sought is broader than what is necessary to remedy the alleged harm).

Third, Amgen's reading of *GEOMC* ignores the Second Circuit's admonition that a defense's factual predicate "will be shaped by the nature of the affirmative defense" and

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that “the facts needed to plead [certain affirmative defenses] may not be readily known to the [counterclaim] defendant, a circumstance warranting a relaxed application of the plausibility standard.” 918 F. 3d at 98. That is precisely the situation here. For example, it is difficult, if not impossible, for Novartis Pharma to know the exact manner in which Amgen could have, but did not, mitigate its supposed damages absent any discovery. Similarly, Novartis Pharma should not be expected, at this early stage, to include detailed factual assertions regarding the speculative nature of Amgen’s damages, or its disproportionately broad request for relief, before Amgen supports its damages assessment.

Amgen’s other arguments in support of its proposed motion are equally unavailing.

Amgen asserts that Novartis Pharma’s third Affirmative Defense—unjust enrichment—is legally insufficient because it should be asserted as a cause of action, rather than an affirmative defense, and because it is unavailable where the parties’ relationship is governed by a contract. Amgen is painting with too broad a brush. Courts throughout this Circuit have found that unjust enrichment is properly asserted as an affirmative defense. *See, e.g., Am. Mfrs. Mut. Ins. Co. v. Payton Lane Nursing Home, Inc.*, No. CV 05-5155 (AKT), 2010 WL 985201, at *2 n.1 (E.D.N.Y. Mar. 15, 2010) (“Payton Lane did raise an affirmative defense of unjust enrichment and I have advised the parties that such defense is viable and that the Court will permit evidence of the same to be introduced at trial.”); *Davis v. Connecticut Cnty. Bank, N.A.*, 937 F. Supp. 2d 217, 243 (D. Conn. 2013) (denying summary judgment on “the Bank’s Eighth Affirmative Defense of unjust enrichment”). Moreover, although Amgen does not raise this issue in its letter, Novartis Pharma’s unjust enrichment defense also applies to Amgen’s tort claim for negligent misrepresentation. In light of the millions of dollars that Novartis Pharma has paid Amgen since the 2017 Collaboration Agreement was executed, Amgen would be unjustly enriched if it were to succeed on its claim that it would not have “expand[ed] the parties’ contractual relationship” had it known of the Sandoz-Alder CMA. [Dkt. No. 13 ¶ 105].

Amgen also asserts that Novartis Pharma’s 1st, 6th, and 7th Affirmative Defenses (failure to state a claim upon which relief can be granted; speculative and uncertain damages; and the relief sought is broader than what is necessary, respectively) challenge elements of Amgen’s Counterclaims—not the entire claim—and must therefore be treated as specific denials rather than Affirmative Defenses. Amgen is wrong: “The obligation to plead affirmative defenses is not limited to complete defenses.” CHARLES A. WRIGHT & ARTHUR R. MILLER, 5 FEDERAL PRACTICE AND PROCEDURE § 1273 (3d ed., April 2019 Update). *See also Sayre v. Musicland Grp., a Subsidiary of Am. Can Co.*, 850 F.2d 350, 355 (8th Cir. 1988) (“Pickwick also argues that only defenses that bar recovery, rather than those that diminish the amount of damages, need be affirmatively pleaded. This assertion is unsound.”). Moreover, affirmative defenses based on a failure to state a claim and

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speculative or overly broad damages are perfectly appropriate. *Sec. Exch. Comm'n v. Toomey*, 866 F.Supp. 719, 723 (S.D.N.Y. 1992) ("[I]t is well settled that the failure-to-state-a-claim defense is a perfectly appropriate affirmative defense to include in the answer."); *GS Plasticos Limitada v. Bureau Veritas*, 964 N.Y.S.2d 59 (Sup. Ct., N.Y. Cty. 2012) (permitting defendant to replead its affirmative defense of speculative damages).

Finally, Novartis Pharma is likely to seek leave to file an amended complaint in the coming weeks to add a claim for sums owing under the 2017 Agreement. To the extent the Court views any of Novartis Pharma's Affirmative Defenses as factually or legally deficient, or instructs Novartis Pharma that any of its Affirmative Defenses should be pled as claims instead, Novartis Pharma could make all necessary changes in its amended pleadings, rather than engaging in inefficient and distracting non-dispositive motion practice.

Accordingly, Amgen's application to file a motion to strike, or treat as denials, Novartis Pharma's Affirmative Defenses, should be denied.

Respectfully Submitted,



Jeffrey A. Fuisz

Copies to Counsel of Record (via ECF Filing)